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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,241

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Li-Qun Wu

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1901 RESEARCH BLVD
SUITE 400
ROCKVILLE, MD 20850-3164

EXAMINER

WONG, EDNA

ART UNIT

PAPER NUMBER

1795

NOTIFICATION DATE

DELIVERY MODE

05/26/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/525,241	WU ET AL.	
	Examiner	Art Unit	
	EDNA WONG	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :February 22, 2005 and May 8, 2006.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The declaration says that the address of William E. Bentley is Annapolis, MD. However, the Application Data Sheet says that the address of William E. Bentley is Silver Spring, MD, and the Bib Data Sheet says that the address of William E. Bentley is Clarksville, MD. Which one is it?

Election/Restrictions

Applicant's election of Group I, claims **1-8**, in the reply filed on April 30, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims **9-19** are withdrawn from consideration as being directed to a non-elected invention.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **1-2 and 6-8** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Redepenning** (US Patent Application Publication No. 2002/0084194 A1).

Redepenning teaches a method of depositing chitosan onto a substrate, comprising:

a) contacting the substrate **6** (= the cathode) [page 2, [0018]] with a solution **8** containing chitosan (= the chitosan containing component of the electrolyte solution) [page 3, [0025]]; and

b) applying an electric current to the substrate sufficient to deposit the chitosan onto the substrate (= a current is passed between the anode and the cathode to cause deposition of the species in the solution adjacent the cathode resulting in the growth of the composite layer on the cathode) [page 3, [0028]].

The method further comprises washing the substrate containing deposited

chitosan with water, a solution with a neutral pH, a basic solution, or an acidic solution (= once the co-deposition of the brushite and chitosan onto the cathode is complete, the cathode is typically subjected to a separate process to convert the brushite portion of the composite coating to hydroxyapatite ($\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$). To convert the brushite to hydroxyapatite, the coated cathode may be subjected to a basic solution such as sodium hydroxide, potassium hydroxide or sodium phosphate) [page 4, [0035]].

The substrate is a metal (= the cathode may comprise an electrically conductive material such as a metal or metal alloy) [page 2, [0018]].

The solution contains chitosan in a concentration of from about 0.0001 to about 30 % w/v (= the chitosan containing electrolyte component will typically have between about 0.10% and about 10% chitosan (by weight)) [page 3, [0026]].

The solution contains chitosan in a concentration of from about 0.1 to about 10 % w/v (= the chitosan containing electrolyte component will typically have between about 0.10% and about 10% chitosan (by weight)) [page 3, [0026]].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

I. Claim **3** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Redepenning** (US Patent Application Publication No. 2002/0084194 A1) as applied to claims 1-2 and 6-8 above, and further in view of **Somashekar et al.** ("Chitosanases- Properties and Applications: A Review", *Bioresource Technology* (1996), Vol. 55, No. 1, pp. 35-45).

Redepenning is as applied above and incorporated herein.

The method of Redepenning differs from the instant invention because Redepenning does not disclose wherein the method further comprises contacting chitosan deposited on the substrate with chitosanase, as recited in claim **3**.

Like Redepenning, **Somashekar** teaches chitosan. Somashekar teaches that chitosanases catalyze the hydrolytic degradation of chitosan. Chitosanases may find important industrial application in the utilization of the enormous chitosan and chitin substrates, available from sea-food-processing units, for the generation of the size-specific chitosan oligomers required particularly in pharmaceutical industries (abstract).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method described by Redepenning with wherein the method further comprises contacting chitosan deposited on the substrate with chitosanase because this would have generated size-specific chitosan oligomers as taught by Somashekar (abstract).

II. Claims **4 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over

Redepenning (US Patent Application Publication No. 2002/0084194 A1) as applied to claims 1-2 and 6-8 above, and further in view of **Spillman, Jr. et al.** (US Patent Application Publication No. 2002/0037383 A1).

Redepenning is as applied above and incorporated herein.

The method of Redepenning differs from the instant invention because Redepenning does not disclose the following:

- a. Wherein the substrate is a semiconductor, as recited in claim **4**.
- b. Wherein the substrate is a conductive polymer, as recited in claim **5**.

Redepenning teaches that a prosthetic device is the cathode (page 2, [0018]).

Like Redepenning, **Spillman, Jr.** teaches applying bio-compatible coatings to medical devices (page 2, [0023]). The starting material that is subjected to an ESA process in the invention may be a polymer that is poly(D-glucosamine) ("chitosan", Fig. 1(f)) [col. 2, [0033] and [0039]]. In a medical device according to the present invention, the substrate is not particularly limited and may be tubing used in dialysis, tubing used in heart lung machines, other plastic tubing, other rubber tubing, bandaging material, composite material, metal material, insulator material, semi-conductor material, artificial hips, titanium substrates, pacemakers, plastic substrates, catheter material, stent material, and other materials used in medical devices (page 5, [0082]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the substrate described by Redepenning with wherein the substrate is a semiconductor; and wherein the substrate is a conductive

polymer because the substrate is a result-effective variable and one having ordinary skill in the art has the skill to determine the substrate that would have provided the success of the desired product, i.e., dependent upon the medical device (MPEP § 2141.03 and § 2144.05).

Furthermore, this is well within the skill of the artisan dependent upon the intended use of the medical device, particularly to the environment to which the medical device will encounter, which would be most suited for the application of the medical device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EDNA WONG whose telephone number is (571) 272-1349. The examiner can normally be reached on Mon-Fri 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Edna Wong/
Primary Examiner
Art Unit 1795

EW
May 19, 2010